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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,967	12/07/2001	Dan L. Eaton	P1447R1	9428

9157 7590 03/21/2003

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,967	EATON ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to an isolated nucleic acid, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.5.

II. Claims 10-13, and 16-21 drawn to an isolated polypeptide, and a composition thereof, classified in class 530, subclass 351.

III. Claims 14-21, drawn to an antibody to the polypeptide, a composition thereof, and an article comprising same, classified in class 530, subclass 387.9.

IV. Claims 16-21, drawn to a composition of an agonist of the polypeptide, and an article comprising same, classification depending upon the chemical entity of the agonist.

V. Claims 16-21, drawn to a composition of an antagonist of the polypeptide, and an article comprising same, classification depending upon the chemical entity of the antagonist.

VI. Claims 22 and 23, drawn to a method of treatment using the polypeptide, classified in class 424, subclass 85.2.

VII. Claims 22 and 23, drawn to a method of treatment using an agonist of the polypeptide, classification depending upon the chemical entity of the antagonist.

VIII. Claims 22 and 23, drawn to a method of treatment using an antagonist of the polypeptide, classification depending upon the chemical entity of the antagonist.

IX. Claims 22 and 23, drawn to a method of treatment using an antibody to the polypeptide, classified in class 424, subclass 139.1.

X. Claim 24 and 26, drawn to a method for determining the presence of a polypeptide using an antibody, classified in class 435, subclass 7.1.

XI. Claim 25, drawn to a method of diagnosis by detecting the expression level of a gene, classification depending upon the method steps.

XII. Claim 27, drawn to a method of identifying a compound inhibiting the *activity* of the polypeptide, classified in class 435, subclass 7.1.

XIII. Claims 28 and 29, drawn to a method of identifying a compound inhibiting the *expression* of a gene encoding the polypeptide, classification depending upon the method steps.

XIV. Claim 30, drawn to a method of identifying a compound mimicking the activity of a polypeptide, classification depending upon the method steps.

XV. Claims 31 and 32, drawn to a method for detecting the presence of tumor in a mammal, classification depending upon the method steps.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The nucleic acid of Invention I is distinct from and unrelated to the antibody, the agonist, and the antagonist of the polypeptide in Inventions III, IV, and V, respectively, because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the products of Inventions III-V because the products may be neither made by nor used in the method.

Invention I is distinct from and unrelated to Inventions VI-XV, wherein the nucleic acid of Invention I is neither made by nor used in the methods of Inventions VI-XV, and wherein each does not require the other.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The polypeptide of Invention II is distinct from and unrelated to the agonist, and the antagonist of Inventions IV, and V, respectively, because they are physically and/or functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The polypeptide of Invention II is related to the methods of Inventions VI and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating the antibody of Invention III.

Invention II is distinct from and unrelated to Inventions VII-XI and XIII-XV wherein the polypeptide of Invention II can be neither made by nor used in the methods of Inventions VII-XI and XIII-XV, and wherein each does not require the other.

The antibody of Invention III is distinct from and unrelated to the agonist, and the antagonist of Inventions IV, and V, respectively, because they are physically and/or functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The antibody of Invention III is related to the methods of Inventions IX and X, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the purification of the polypeptide of Invention II.

Invention III is distinct from and unrelated to Inventions VI-VIII and XI-XV, wherein the antibody of Invention III can be neither made by nor used in the methods of Inventions VI-VIII and XI-XV, and wherein each does not require the other.

The agonist of Invention IV is distinct from and unrelated to the antagonist of Invention V, because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The agonist of Invention IV is related to the methods of Invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for identifying a receptor for the polypeptide of Invention II.

Invention IV is distinct from and unrelated to Inventions VI and VIII-XV, wherein the agonist of Invention IV can be neither made by nor used in the methods of Inventions VI and VIII-XV, and wherein each does not require the other.

The antagonist of Invention V is related to the methods of Inventions VIII, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for identifying a receptor for the polypeptide of Invention II.

Invention V is distinct from and unrelated to Inventions VI, VII, and IX-XV, wherein the antagonist of Invention V can be neither made by nor used in the methods of Inventions VI, VII, and IX-XV, and wherein each does not require the other.

Inventions VI-XV are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and is for a different purpose, such that they require separate searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
3/12/03